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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/399,003	09/20/1999	HOLLY HOGREFE	04121.0116-0	1754
22852	7590	09/27/2002	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20006			TAYLOR, JANELL E	
		ART UNIT	PAPER NUMBER	
		1634	17	
DATE MAILED: 09/27/2002				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/399,003	HOGREFE ET AL.
	Examiner	Art Unit
	Janell Cleveland Taylor	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 58-95 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 58-95 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \*    c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input checked="" type="checkbox"/> Other: <i>Detailed Action</i> .

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Claims 58 and 84 were elected without traverse in paper #12, there being no allowable generic or linking claim.

### ***Claim Objections***

2. Claim 58 is objected to because of the following informalities: the claim is drawn to PEF protein P45, but since this is the first occurrence of the term "PEF" in the claims, the claim should be amended to recite what PEF stands for; namely "Polymerase Enhancing Factor". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 58 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is drawn to a DNA construct comprising a sequence encoding PEF protein P45, but it is unclear what is encompassed by this protein. Absent the teaching of a specific SEQ ID NO to identify the sequence encoding PEF protein P45, one of ordinary skill in the art would not be apprised what is encompassed by the claim.

5. Claim 84 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim states "A DNA encoding a PEF activity..." It is not

clear what this activity is, or how the DNA may "encode an activity", as DNA encodes amino acids, not activities. Appropriate correction is required.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 58 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for PEF protein P45 as defined by SEQ ID NO: 70, as found on page 43 of the specification, does not reasonably provide enablement for any PEF including partially synthetic copies or analogs of the naturally occurring polymerase (as PEF is defined in the specification, page 5, lines 23-24). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Case law has established that "(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that "(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". Furthermore, the Court in *Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001 held that "(l)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement". In the instant

case, the specification has identified only a single PEF P45 nucleotide sequence, yet the claims encompass a huge genus of possible sequences wherein the sequences may be from other organisms, may be of any length and may share very little sequence identity with the sequences of the *Pyrococcus furiosus* PEF P45 nucleic acid. Thereby, the scope of the claims do not bear a reasonable correlation to the scope of enablement provided by the specification. Furthermore, because the specification does not identify particular regions in the P45 gene which could be modified without altering the functional activity of the polymerase, and because it is expected that even a single nucleotide alteration may significantly alter the functional activity of these sequences, undue experimentation would be required to identify variants which maintain the activity of a PEF P45 protein.

8. Claim 84 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a DNA encoding a PEF activity comprising one or more of SEQ ID NOS: 32-35, 82, 83, or 70, does not reasonably provide enablement for degenerate variants thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Case law has established that "(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that "(t)he scope of the claims must bear a reasonable correlation to the scope of enablement

provided by the specification to persons of ordinary skill in the art". Furthermore, the Court in *Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001 held that "(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement". In the instant case, the specification has identified only those specific SEQ ID NOS found in the claims, yet the claims encompass a huge genus of possible sequences wherein the sequences may be from other organisms, may be of any length and may share very little sequence identity with SEQ ID NOS found in the claims. Because a "degenerate variant" of the sequences may encompass not only fragments of the SEQ ID NOS but also mutations of the sequences, the genus encompassed is huge. Thereby, the scope of the claims do not bear a reasonable correlation to the scope of enablement provided by the specification. Furthermore, because the specification does not identify particular regions in the sequences which could be modified without altering the functional activity of the polymerase, and because it is expected that even a single nucleotide alteration may significantly alter the functional activity of these sequences, undue experimentation would be required to identify variants which maintain the activity of the given SEQ ID NOS.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 84 is rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (USPN 5,474,796).

The claim is drawn to a DNA encoding a PEF activity comprising a) one or more of SEQ ID NOS 32-35, 82, 83, or 70, b) a sequence hybridizable to the complement under stringent conditions, or c) a degenerate variant thereof.

Brennan teaches every possible oligonucleotide having 10 nucleotides. This includes every possible permutation of a 10-mer, and would anticipate both a sequence hybridizable to the complement under stringent conditions (as the claim does not recite that the sequence which is hybridizable to the complement need be greater than 10 nucleotides long), as well as degenerate variants thereof, which also may be any length or composition. Therefore, Brennan fully anticipates the claim.

### ***Conclusion***

Any inquiries of a general nature relating to this application, including information on IDS forms, status requests, sequence listings, etc. should be directed to the Patent Analyst, Chantae Dessau, whose telephone number is (703) 605-1237.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janell Taylor Cleveland, whose telephone number is (703) 305-0273.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (703) 308-1152.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1634 via the PTO Fax Center using (703) 872-9306 or

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872-9307 (after final). The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989.)

Janell Taylor Cleveland

September 17, 2002



W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600